

Table 1

Treatment Effect Versus Level of Her-2 Expression

	Single-Arm Trial	Treatment Subgroups in Randomized Trial			
	Herceptin™	Herceptin™ + Paclitaxel	Paclitaxel	Herceptin™ + AC	AC
Overall Response Rate					
2+ Overexpression	4% (2/50)	21% (5/24)	16% (3/19)	49% (14/35)	43% (18/42)
3+ Overexpression	17% (29/172)	44% (30/68)	14% (11/77)	53% (57/108)	36% (35/96)

Table 2

Pellets	Fmol/mg ELISA	Fmol/mg Image Analysis
MCF7 2 12167	220.0	262.0
MCF7 1 12167	236.0	307.0
MCF7 2 01148	188.0	183.0
MCF7 3 01148	179.0	207.0
ERC 1 01148	348.0	315.0
ERC 3 01158	358.0	338.0

Table 3
Correlation between ELISA and Image Analysis Values
of Estrogen Receptor in Patient Tissues

<u>Tissue</u>	<u>Fmol/mg</u> <u>ELISA</u>	<u>Fmol/mg</u> <u>Image Analysis</u>	<u>%Positive Area</u> <u>Image Analysis</u>
95-1014	62	70	25
95-1052	23	36	43
95-1071	186	105	45
96-1130	34	34	0.6
96-1142	35	122	51
96-1268	170	150	34
96-328	>250	238	45
96-361	109	85	40
97-029	256	91	36
97-1161	>167	240	65
97-1234	>294	262	51
97-1275	21	93	41
97-1350	226	217	55
97-1469	38	56	26
97-1497	0.5	0	0
97-234	2.5	0	0
97-242	27	40	6
97-573	11.5	33	2
98-011	135	77	27
98-025	>454	556	78
98-035	143	150	46
98-043	25	114	47
98-077	>227	318	65
98-078	305	23	2
98-087	56	55	23
98-098	77	73	26
98-103	178	160	15
98-134	304	10	0.2
98-159	10	18	0.2
97-341	>161	191	70
97-417	90	125	19
97-446	250	201	55
97-647	0.94	0	0
97-1053	76	71	14
97-1111	273	217	56

Table 4
Results of HER-2/neu ELISA and HER-2/neu Quantitative Image Analysis (IA)
on Five Breast Cancer Tissues

Tissue I.D.	ELISA fm/μg	IA fm/μg
98-510	0.23	0.30
98-511	1.74	1.12
98-551	0.05	0.08
98-594	0.16	0.76
98-664	0.17	0.20

Table 5
Summary of Tumor Marker Distributions

Tumor Marker	Threshold	Range
HER-3	0.79	0.01 ~ 2.80
HER-4	0.08	0.01 ~ 0.89
Heregulin	0.22	0.01 ~ 1.08
P-P38-1	22.00	0 ~ 0.05

Table 6A
Calibration of DU 145
(250,000 receptors per cell)

Cell Line	Receptors per cell
SKBR3	60,000
A549	85,000
PACA	150,000
PC3	205,000
AU565	1,000,000
MDA-MB 468	2,000,000

Table 6B
Quantitation of EGFR by Image Analysis: Tissue

Tissue	Source	Number of Receptors
98-421	Bladder Cancer	47K
98-348	Breast Cancer	31K
99-1746	Breast Cancer	43K

Table 7
HER-2/neu ELISA Quantitation Data and HER-2/neu Image Analysis
Quantitation (IA) Data of Four Cell Pellets

Pellet	ELISA fm/μg	IA fm/μg
MCF-7	0.28	0.24
MCF&/HER-2	0.53	0.55
MDA-MB543	1.31	1.37
SKBR3	>3.07	3.04

Table 8A
Calibrator Cells

Cell Line	Receptors/cell	fm/μg
MDA-MB-361	92,000	0.19
SKBR 3	2,400,000	3.90
MCF7	60,552	0.14
AU537	2,585,637	4.20

Table 8B
Tissues

Specimen	Receptors/cell	fm/μg
99-1908	611,066	1.02
99-1973	1,202,527	1.98
99-1976	2,567,438	4.20

Table 9

Prognostic Role of HER-4, Heregulin, and JNK-p38 in Patients with Stage II Breast Cancer Treated with Doxorubicin-Based Adjuvant Chemotherapy

Tumor Marker	Total	# With Records Available	5-Yr Disease Free Survival (%)	P
	35	20	57	
HER-4				
<0.08	15	4	80	<0.01
>0.08	20	16	39	
Heregulin				
<0.245	18	6	78	<0.01
>0.245	17	14	35	
P-p38				
0	24	16	46	0.06
>0	11	4	81	